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In order to provide a quality remote examination in ophthalmology, a video stereo slit lamp must be developed. This slit lamp must beof sufficient quality to allow differentiation between a red blood cell and a white blood cell floating in the anterior chamber of the human eye.

Using present technology with modification, we propose developing such an instrument as a first step in evolving a complete set of equipment to allow a remote technician-guided ophthalmology examination.

The equipment was developed and we created appropriate protocols for equipment utilization. We were able to verify that there was a very strong correlation for corneal and intraocular diagnoses between the remote viewing examination and the direct examination. The areas that correlated weakly were related to inexact descriptions of minor lid and conjunctival abnormalities. No one who looked at the patient and at the incredibly high quality photographs felt that they were limited diagnostically by the visual images presented.

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Randall J Olson, MD - 6-27-02

PI - Signature Date

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OVERVIEW

In March 1996, Wayne Imbrescia and Randall J. Olson, MD traveled to Fort Detrick for discussions regarding a proposal for the design and development of a High Resolution Digitized Stereo Video Slit Lamp in conjunction with the U.S. Army Medical Research and Materiel Command Teleophthalmology project.

The purpose of this project was to provide a quality, remote examination in ophthalmology via video stereo slit lamp. It was determined that the slit lamp must be of sufficient quality to allow differentiation between red blood cells and white blood cells floating in the anterior chamber of the human eye. This instrument was viewed as the first step in evolving a complete set of equipment to allow a remote technician-guided ophthalmology examination. They felt that somewhere in the not too distant future physician's offices would be fully computerized with medical records, would will include the digitized stereo photos with videos, laboratories, pharmacies and regional centers all linked together. Complete examinations would be undertaken without the need for appointment and would be handled in a matter of minutes with technicians running the testing apparatus and coordinating all activities. Results would be reviewed remotely for routine screening by ophthalmologists, with responses generated by email, the postal service or telephone. This concept would allow ophthalmologists to easily and accurately screen a large percentage of the patient population, particularly those in remote locations.

Performing comprehensive eye examinations with electronic diagnostic equipment requires significant hardware and software development. The final goal was to have all information digitized, computerized and easily managed by relatively inexpensive technicians in a labor efficient fashion. The stereo digitized video slit lamp would be the core of any ophthalmic examination for the future by using high-resolution stereo monitors and digital data compression. Such digitized information would become the basis for diagnostic enhancements and computer programs both to decide what the pathology might be and to develop a computerized differential diagnoses, and examples of similar pathology, all from the computerized data base. The vision of this technology also included the concerns by the military that any service person, anywhere in the world, would have access to a detailed slit lamp examination to determine extent of injury or concern for needed follow up and surgical intervention. The ability to produce a high quality digitized stereo image anywhere in the world would allow detailed consultation of a patient at any remote site.

A partnership between the John A. Moran Eye Center, (JMEC) University of Utah and the U.S. Army Telemedicine Advanced Technology Research Center (TATRC) was established on June 2, 1997. The long term strategic goal of this relationship was to promote the development of essential ocular instrumentation capable of supporting comprehensive diagnostic ocular exams remotely.

Once the grant was awarded, the Department of Ophthalmology at the University of Utah Health Sciences Center, retained Evans and Sutherland to develop this stereo video slit lamp. Evans and Sutherland reported that from September 1997 through November 1997 they actively sought a partnership with other industry members to develop this technology. During the American Academy of Ophthalmology Conference in October 1997, Evans and Sutherland sent representatives to network with various industry members. Discussions were centered on possible industry partners and possible system components for this project. The representatives were able to visit the conference exhibits and investigate several

companies that offered stereoscopic slit lamps. The search for an industry partner continued and became more lengthy and difficult than initially anticipated. Evans and Sutherland then held discussions with Nikon, however, plans of the two companies did not seem to converge. They also sought appropriate camera technology for this project. At one time they felt an electronic camera from Kodak would suffice, however, the Kodak camera was found to be inadequate for this application. Because of the difficulties encountered in finding the appropriate partners and available technology, the program slipped behind an estimated three and a half months. Little additional progress could be made until a selection of these two components was formalized. Costs incurred during this period of time included 32 hours of labor grade extended costs totaling $6,017.00 for September and $8,869.00 for October.

Through contacts made at the Academy of Ophthalmology meetings, representatives from Evans and Sutherland were introduced to Avi Grinblatt, CEO of the Advanced Visual Instruments, Inc., based in New York City. It was at this point we realized that this technology already existed. Mr. Grinblatt had clearly developed the technology we were seeking to develop ourselves. Rather than continue on this course with Evans and Sutherland, we determined that we could tap into this existing technology. Through a series of meetings and upon mutual agreement, we terminated our contract with Evans and Sutherland to pursue this effort.

Through negotiations, we found that we could partner with Mr. Grinblat in pursuit of this project. This was an extremely fortunate turn for all involved and following extensive analysis of international government, academia and industry effort, Advanced Visual Instruments, Inc., was determined to be the leader in the development of this specific instrument as well as having the capability of using this technology for remote operation.

During the first half of 1998, subcontracting issues with Advanced Visual Instruments were resolved and the project was positioned to move forward by August 1998. Final work statement revision, itemized equipment lists, and budgets were resubmitted to the U.S. Army Medical Research Acquisition Activity Office and approved. Systems equipment was ordered from Advanced Visual Instruments for the John A. Moran Eye Center and Walter Reed Army Medical Center. The clinical studies protocols for JMEC and WRAMC were approved and are contained in the "Clinical Trials" section of this report. **(Appendix A - Phase I Cost Estimate)**

The John A. Moran Eye Center implementation team made a site visit to Walter Reed Army Medical Center from January 27 through January 29, 1999 to exchange information on equipment operation, coordinate data collection for clinical trials and assist in actual patient exams with an Ophthalmology Grand Rounds presentation. Data comparison of clinical trials between JMEC and WRAMC resulted in further refinement of image capture and illumination techniques. The clinical trials were to begin January 1999 and were to be conducted through March 1999. Expenditures to the contract at this point were $29,980.73.

Evaluation of the capabilities of this existing technology, to produce and archive ocular images of diagnostic quality, as well as determining what modifications and additions would further enhance this capability, was accomplished through multi-site clinical viability trials. Funding from TATRC ,as well as JMEC, was designated to purchase two High Resolution Digitized Stereo Video Slit Lamp systems from Advanced Visual Instruments, Inc. One slit lamp system was delivered and installed at Walter Reed Army

Medical Center, under the direction of TATRC. The other, at the John A. Moran Eye Center, under the direction of the University of Utah. The slit lamp systems are the property of these respective entities with funding for one of the slit lamps by the Moran Eye Center, and funding of the second slit lamp by the Army U.S. Army Medical Research and Materiel Command . Equipment installation at the John A. Moran Eye Center, and Walter Reed Army Medical Center was completed by December 1998. With the "off-the-shelf" existing technology available, through Advanced Visual Instruments, Inc., clinical viability trials were to be completed by the end of February 1999.

EQUIPMENT:

The contractor assembled two operational prototypes systems, using a combination of off the shelf items, with the following specifications:

- High quality slit lamp(Haag Streit BQ 900, with Haag Streit Photo Upgrade Package I) a high-resolution digital camera optically adapted to slit lamp.
- Synchronized flash system
- Indirect lighting source for the anterior segment of the eye
- IEEE 1394 Connector for downloading images
- 8 PCMCIA cards
- Workstation processor equivalent or greater then 900 MHz Pentium
- 1 GB RAM, 36 GB hard drive, 20/48x IDE CD_ROM reader
- 4x/2x/24x IDE CD-ROM writer
- 64 MB video card
- PCMCIA card reader, 10/100 network card
- FAX modem card 56 KB
- USB port, IEEE 1394 port
- 21-inch passive high-resolution color monitor, with vertical refresh rate of 70-90 MHZ with passive screen for 21 inch included.
- Archival software for storing images, Windows NT compatible.
- 2 laptops with Pentium 750 or greater/compatible CPU with 512 RAM, 356 GB hard drive, 32x CD-ROM reader
- USB port, Imation 120 floppy port, 1394 card and port with driver, Windows NT, Internal 56K v.90 capable fax modem, 10/100 fast Ethernet PC cart, and spare 79 watt Li-Ion battery

The high resolution slit lamp yielded clear, well-defined images of the anterior segment of the eye, including the corneal stroma. Cell/cells in the anterior segment were visualized on digital photos. Detail of the iris and lens was noted to include crypts, lens opacities, and posterior capsular cataracts. The images were readily transferable to a passive stereo viewing system. The viewer used filtering glasses, viewing a polarizing screen located on the monitor. The archival software permitted thumbnail picture evaluation, easy storage of selected imaged and Adobe Photoshop archival retrieval.

This equipment clearly demonstrated and confirmed the proof of concept for this project. The already existing "off the shelf" technology provided by Advanced Visual Instruments, was able to provide one optical adapter for stereo views and one high magnification adapter.

The optical camera adapter magnified at 120 times greater than the slit lamp, which in itself magnified at 40, equaling magnification capability of 4800. This capability could easily discern red blood cells and white blood cells. This technology also included microfocus and x-y maneuverability on the screen, with independent focusing capability on the screen for additional adjustments for viewing purposes. Therefore, a physician/technician could work with the patient at the lower magnification while the adapter viewed the images at the higher magnification of 4800.

(Appendix B – Training Manual). (Appendix C – Equipment Photographs)

CLINICAL TRIALS

Introduction:

It was envisioned that the one area of ocular instrument development having the greatest potential for advancing the field of Ocular Telehealth was the High Resolution Digitized Stereo Video Slit Lamp. The objective of the project was to evaluate the capabilities of the most advanced system currently available and to determine diagnostic clinical viability through proof of concept, multi-site clinical trials. Diagnostic clinical viability was defined as sufficient image quality to allow differentiation between red and white blood cells floating in the anterior chamber of the human eye.

The results of these clinical trials would either validate the existing technology's capabilities of producing and archiving diagnostic quality images or identify what modifications to the existing technology would be required to achieve this level of imaging. Advanced Visual Instruments provided and installed two systems as well as the technical support during the clinical trials. Modifications required to enhance the abilities of these systems during the clinical trials was documented, evaluated and facilitated through the University of Utah John A. Moran Eye Center.

Any modifications to the system because of information derived from clinical studies would be granted government purpose licensing rights to the modifications. All expenses for the clinical trials were paid by the John A. Moran Eye Center.

Phase I of this project was the initial proof of concept. Phase I demonstrated the locally operated slit lamp, with stereo viewing system and provided an initial image archival system. The clinical trials were conducted at Walter Reed Army Medical Center and the John A. Moran Eye Center between the months of November 1998 and February 1999.

Phase II was the remote operation proof of concept. Phase II demonstrated remote operation of the Phase I system. Phase II produced a system that was capable of conducting remote slit lamp examinations between Walter Reed Army Medical Center and the John A. Moran Eye Center. Phase II was a separate project to commence once clinical viability was adequately demonstrated in Phase I.

Phase II was a future phase outside the scope of the initial proof of concept Phase I demonstration system. This phase was established to demonstrate the ability for eye care professionals at the Moran Eye Center to engage in remote operation of the camera slit lamp optical interface adapters at Walter Reed Army Medical Center. In understanding the complexities associated with remote operation of all slit lamp functions, the

intent of this phase would be to focus on remote operation of these functions, specifically contained in the camera/slit lamp optical interface adapters. These functions were defined as micro-focus, X-Y axis positioning and zoom capabilities.

The concept demonstration system included a standard commercial slit lamp fitted with a high-resolution color video camera system. The camera system fed video to both a stereo viewing system for direct viewing and an image archival system. The image archival system was controlled by proprietary software developed by Advanced Visual Instruments, Inc., running on a Macintosh or PC workstation that controlled the image archival system. The phase I concept demonstration system required a local operator to adjust the slit lamp.

Study Design:

The overall project was organized into two phases. The initial phase, the design and development of the prototype equipment was completed in July 1998. The second phase was designed as a prospective observational study. A total of 50 subjects (100 eyes) were evaluated. The Investigators were masked as to the patient identity when evaluating the videos.

Patient Selection Criteria:

Patients were of legal age and enrolled from consecutive patients presenting in the Investigator's clinics with one or more of the following diagnoses:

- Blepharitis
- Lid mass
- Conjunctival pigment
- Follicles/papillae
- Pingueculum/pterygium
- Corneal scar
- Punctate keratitis
- Iridotomy
- Iris lesion
- Keratic precipitate
- Posterior synechiae
- ASC cataract
- PSC cataract

Both of a patient's eyes were enrolled in the study. Each eye was identified with a distinct study ID number.

Study Procedures:

Patients were treated according to the routine usually followed in the Investigator's clinic, consistent with the reason for the visit. As the Investigator began his exam he recruited appropriate patients for the study and obtained signed informed consent. Patients were then scheduled for a clinic visit with an ophthalmic photographer who was trained in performing the digital slit lamp exam according to standard protocol. The

photographer obtained still images of standardized exam fields. Each video was then labeled with the patient eye study ID#, date and name of the in-person examiner. **(Appendix D – Protocol Notes and Exam Forms)**

Data Analysis:

The patient information was entered into spreadsheet format. Overall demographic and clinical characteristics of the patient population were described, using means with standard deviation and proportions to include age, race, gender, and diagnoses.

For analysis of the slit lamp exam, the sampling unit was the diagnosis. Each eye had at least one diagnosis. Inter-observer reliability for the slip lamp exam and intra-observer reliability between the in-person exam and the video exam was described with Kappa statistic.

Using the in-person exams as the gold standard, the proportion of correct diagnoses made with the video exam was described using proportions with 95% confidence interval.

Administrative Responsibilities:

The Investigators were responsible for recruiting subjects from their clinic populations and obtained informed consent. Source documentation of exam findings included the patients medical chart, exam videotape and the study exam forms used to record video observations.

DATA/CLINICAL TRIALS REPORT ANALYSIS:

In January 1999 following the site visit a comparative data exchange for each patient was to be reviewed by clinical faculty to validate credibility of data. Data on the first four patients from the John A. Moran Eye Center and three patients from Walter Reed Army Medical Center were examined. Efforts were then made to increase patient enrollment at both sites. It became evident as the information was compiled that we needed to develop consistent nomenclature between physician groups at both sites to assist in reducing data variables.

Expenditures during the month of January totaled $144,014.60. Total expenditures against the contract to date were $173,995.33.

Clinical trials were well underway by February 1999, at both Walter Reed Army Medical Center and the John A. Moran Eye Center. By mid-March 1999, twenty (20) subjects were enrolled in the study; 8 from WRAMC and 12 from JMEC. Both sites continued to enroll subjects into the study with the goal being 50 subjects (100 eyes). Parallel processes continued between the two entities with image quality comparison from the clinical trials resulting in further refinement of image capture and illumination with WRAMC.

Although the subject enrollment continued and systems training was completed, the original schedule required adjustment. A request was made to TATRC to extend the clinical trials through May 1999 in an effort to enroll the 50 subjects originally proposed.

Analysis of the current protocols yielded some issues that required attention. These issues included:

- Mastering the imaging and illumination systems took longer than anticipated resulting in an average image/exam capture time of one hour and fifteen minutes.
- Initial findings confirmed stereo video application is an essential element of diagnostic imaging.
- Subject enrollment, exam time, investigator availability and the complexity of the illumination and imaging systems resulted in delays in the clinical trials.
- It was also advised that the decision to exercise the option to purchase an additional system be extended until the clinical trials were completed.

At the end of March 1999, a total of 25 subjects had been enrolled in the study for both locations; 13 from WRAMC and 12 from JMEC. Application was made to the U.S. Army Medical Research Acquisition Activity for contract modification of the term of contract. The application requested an extension of 6 months to complete the clinical research. Stereo video image viewing was enhanced through the addition of upgraded crystal eyes goggles. Illumination techniques continued to be refined. At this point the imaging and illumination techniques were felt to be improved resulting in a decrease of image/exam capture times by 15 minutes. Image capture/exam times were averaging one hour. Progress was encouraging and the project teams were striving to continue the reduction of imaging time while maintaining image quality.

There was a project team meeting in April to review the status of the project and to prepare for the ATA international conference in April 1999. The technology was to be introduced at the ATA International meeting held in Salt Lake City, Utah. Expenditures remained constant. There were no additional expenditures during March and April..

During April through June 1999 the clinical trials continued. Both institutions identified a definitive need to use standardized vocabulary specific for ophthalmic pathologies. A collaborative effort was undertaken to evaluate the existing "Iowa System" to determine if it could meet project needs. Presentation of preliminary clinical research results as well as study design and equipment configuration was presented at the American Telemedicine Association and International Consortium for Ocular Telehealth (ICOT) in April 1999.

Approval of contract modification to extend the clinical research time of completion was approved, changing the deadline from March 1999 to September 1999. Review of the preliminary clinical research results and feedback to ophthalmologists with improvement of the quality of images captured, was completed. The image capture times continued to improve with refinement of imaging and illumination techniques. The focus for the next quarter was to be on the identification and refinement of standardized diagnostic vocabulary, and continued evaluation of the 90/10 beam splitter to optical camera interface and the lens holder for retinal imaging with addition of a 90/10 beam splitters to optical camera interfaces. Prototypes were developed and were tested at JMEC.

As of June 30, 1999, 41 subjects were enrolled in the study with 21 from WRAMC and 20 from JMEC. Expenditures remained constant.

Enrollment of subjects into clinical trial was completed by September 21, 1999. A total of 73 subjects had been enrolled in the study, 31 from WRAMC and 42 from JMEC This effort exceeded the goal of 50 subjects (100 eyes). Standardization of vocabulary was accomplished and used at both institutions to define specific ophthalmic pathologies, which allowed consistent grading of data. Both WRAMC and JMEC were able to reach each other's images utilizing standardized 16 fields of image capture. All indications were that the clinical trials went well and that documentation of the clinical viability was established. It was planned that complete cross reading of all subjects would be complete by October 8, 1999 with a complete statistical analysis no later than October 15, 1999. It was planned to present the findings of the clinical trials at the American Academy of Ophthalmology meeting in Orlando, Florida, October 24, 1999. Expenditures remained constant at $173,995.33.

By December 1999 the cross reading of all subject names was complete and the statistical analysis was in the final stages as the clinical trials were complete. The initial findings of the clinical trials were presented at the American Academy of Ophthalmology meeting in October 1999.

Expenditures ended at $173,995.33. The results of the clinical trials are found in appendix

Data Collection Analysis:
Sue Toledo, Biostatistician, submitted a report in October 1999 on the data collection analysis. Her comments included the following:

- Data was sorted by reviewer to gather all analysis by the same person.
- There was a slight variation in the conjunctiva/sclera data, because there was a category titled "conj lesion/cyst." This did not occur in data received, however, case #39 included this under "other".
- Some assumptions had to be made in data interpretation because the descriptive words were separated by slashes or commas, because there was no indication that this referred to one disease process or more than one.
- The principal data constructed to make comparisons was the number of abnormalities detected for each principal part of the eye.
- Sensitivity, specificity and positive predictive values were also calculated for each teleanalysis and each part of the eye. The inpatient analysis was taken as the "gold standard".
- Where focus was on the detection of abnormalities in major sections of the eyes, initial calculations of sensitivity, specificity and positive predictive value just compared whether or not the teleanalyst and inpatient analyst had detected abnormalities in the same parts of the eye (i.e., the nature and number of the abnormalities for each part were not taken into consideration. **(Appendix E – Eye Examination Photographs)**

Data Observations/Comments:

Observation and comments of the variability of the clinical data were documented. It was felt that the inter-examiner variability was the largest contributor to the low correlation in the data. The physicians tended to approach the study with their own inherent biases of what is or is not clinically significant. Age related changes are normal in a given age group, but on masked review, the observer did not know the age

of the patient other than the visual clues seen on examination. Therefore, such findings may be noted on review but not in person exam. The other source of variability is the quality of photographic images. This is crucial to distinguishing between pathologies, determining the depth of a finding in the slit beam or reflection, on a flat image (stereo video helps here, but the images seem to be even more problematic for an inexperienced photographer than the still shots). Usually several fields must be viewed to make a diagnosis, so all images must be of good quality.

It may not show on statistical analysis, but observing examinations revealed the fact that the reviewer also had a learning curve for interpreting the images. On the data, result sheets vary with more findings found in the images than in person exams. It is possible that the high-resolution camera may allow you to see more than you would in person.

The observer felt that future studies using current data and images should be written up for possible publication. Images should be cataloged in a database using standardized nomenclature. Future study proposals for the high resolution stereo video slit lamp might include complication of lens opacity images, compilation of eyelid lesion images with histopathology sections and access feasibility of remote management of post PKP patients using digitized exams. **(Appendix F – Results of Teleophthalmology Experiment)**

CLINCAL TRIALS/CONCLUSION:

The clinical trials had enough patients that we were able to reach some conclusions in regards to the validity of this approach. While correlations, in regards to pathology of the lid and conjunctiva, either did not exist or were very weak, it is obvious from the review of the different diagnoses listed that they simply represented a difference of opinion in regards to clinically minor variations that are exceedingly common in all older patients. None of these variations were of any clinical significance and could have largely been avoided by a stricter glossary with more specific definitions of each diagnosis.

As we moved into the anterior chamber, iris and lens, as well as the cornea, the correlation was extremely strong and these are the diagnoses of clinical significance. Although we used direct patient examination at the gold standard, we have no evidence from the study whatsoever that the quality of the examination from the remote view was not superior. In fact, having been involved in the study, and now with additional studies with this technology, the opportunity to freeze frame complex pathology and use magnification impossible in direct patient examination are distinct advantages and provide diagnostic opportunities not possible with a live patient. Certainly any technology deserves appropriate protocol creation for image capture and experienced technicians to utilize this equipment. It is also clear, however, that neither issue is particularly difficult and an experienced technician can capture the pathology with high precision and detail not possible in a live patient. We therefore conclude that this technology is fully capable of documenting and diagnosing anterior segment disease from the remote standpoint that is likely equivalent and possibly superior to a live situation. Decreasing the cost of a large bandwidth transmission and increasing reimbursement to allow the development of such technology will see an explosion of such approaches that will become a vital part of medical care in the future.

CONTRACT MODIFICATION/EXTENSION:

In March 2000, the U.S. Army Medical Research and Materiel Command representative requested that we modify our contract to extend the original time from June 2, 1997 to October 1, 2000, to June 2, 1997 to December 31, 2000. Research was to end on November 15, 2000 rather than the original end date of May 1, 2000. The budget was revised and incorporated into this modification. The scope of work was replaced to reflect an additional purchase of two operational prototype systems to be assembled by the contractor. This was to be done using a combination of off-the shelf items with the specifications listed on the revised Scope of Work.

System I (flash option) would consist of an FS-3V Nikon zoom photo slit lamp with a Nikon D-1 digital camera. System one would be required to have an additional indirect lighting source for illuminating the anterior segment of the eye.

System II (non-flash option) would consist of a Haag Streit BQ900 photo slit lamp with a Kodak DCS-620x digital camera optically adapted to the slit lamp. System two would have an enhanced illumination system, which would be coupled to the slit lamp for lighting optimization. In addition a high-resolution video monitoring system was to be adapted to system II to assure high quality digital images.

Both camera requirements were specifically called out in detail, as well as two laptops to accompany this system. **(Appendix G – Option to Purchase Additional Equipment)**

The high resolution slit lamp systems were to yield clear well-defined images of the anterior segment of the eye to include the corneal stroma. Cell/cells in the anterior segment capability to visual on digital photos. Detail of the iris and lens including crypts, lens opacities and posterior capsular cataracts was also required. The images were to be readily transferable to a passive stereo viewing system, with filtrating glasses viewing a polarizing screen monitor. The archival software was to permit thumbnail picture evaluation with easy storage of selected images.

The contract deliverables were to be shipped to Telemedicine and Advanced Technology Research Center (TATRC) in Ft. Detrick, MD and to the Brooke Army Medical Center in Fort Sam Houston, Texas.

APPENDICES

SUBCONTRACTOR ADVANCED VISUAL INSTRUMENTS, INC.,
PHASE 1 - COST ESTIMATE
Line Item Budget
(This line item budget covers only phase one activities and delivers two complete systems)

Manufacturer/Item #	Purchases	Cost	USA/TATRC Contribution	JMEC Contribution
Sony DKC-5000/PC1	Digital slit camera with control unit, SCSI interface, software	$ 21,900.00	$ 10,950.00	$ 10,950.00
Sony DKB-58008	8 Frame Memory Upgrade Board for DKC-5000	6,300.00	3,150.00	3,150.00
Sony PVM-8043	8" High Resolution Color Monitor: Over 450 lines	2,960.00	1,480.00	1,480.00
Sony 48NCQUAD	BNC Cable: 4BNC Male Quad to 4 BNC Male Quad	183.60	91.80	91.80
Sony DXC - 760MD	Color Video Camera: 3 2/3" CCD, 750 TV lines with control unit	44,800.00	22,400.00	22,400.00
Sony PVM-20M2MD	19" High Resolution color video monitor: Over 600 lines	5,170.00	2,585.00	2,585.00
Sony 48CQUAD	BNC Cable: 4BNC Male Quad to 4 BNC Male Quad	550.80	275.40	275.40
Visual Research	Stereo Video Control Unit with 2 goggles, playback unit	16,000.00	8,000.00	8,000.00
Sony UP-D8800/C	Full Page (8.5x11) Digital Color Printer: scsi ,ethernet, apple talk	24,000.00	12,000.00	12,000.00
Sony DKR/700/RMC	Digital Still Recorder w/wired remote keypad	9,340.00	4,670.00	4,670.00
Sony FS-20	Foot switch for DKR-700	50.00	25.00	25.00
Sony MMD-140	D-DATA 140MB discs for DKR-700	200.00	100.00	100.00
Sony SVO-9500MD2	S-VHS Video Recorder w/RS-232C interface board	6,790.00	3,395.00	3,395.00
Sony SVRM-100A	Wired remote control with jog/shuttle search: for SVO-9500	670.00	335.00	335.00
Sony FS-20	Foot switch for DKR-700	50.00	25.00	25.00
Sony 48NCQUAD	BNC Cable: 4BNC ale Quad to 4BNC ale Quad	550.80	275.40	275.40
Sony S4P	S-video (Y/C) interconnect cable (2M)	204.00	102.00	102.00
AVI FIB-OPT	Fiber optics: Stage 1 prototype:illuminator box & central bundle	6,800.00	3,400.00	3,400.00
HS 900 BZ	9000.001ONH BQ slit lamp w/stand &casters No Hrby lens	20,349.00	10,174.50	10,174.50
HS 9004.4	Applanation tonometor for BQ slit lamp	2,106.00	1,053.00	1,053.00
HS 9007.10.70/30	Beam Splitter 70/30	2,484.00	1,242.00	1,242.00
HS 9007.4C	Cross Hair eye-piece	1,278.00	639.00	639.00
HS 9007.5	Stereo Variator	1,638.00	819.00	819.00
HS	Cable conduit for video cable	495.00	247.50	247.50
AVI	Light Source	2,600.00	1,300.00	1,300.00
AVI	Dual Fiber bundle Proto-type, one of a kind	3,000.00	1,500.00	1,500.00
AVI	Micro-focus stereo twin adapters for DXC-760 cameras	18,000.00	9,000.00	9,000.00
AVI	Micro-focus, micro-XY, and micro zoom adapter for DKC-5000	10,000.00	5,000.00	5,000.00
Apple G3300MHZ	256MB RAM, (2) 9 Gig SCSI III HD,21" Radius press view monitor +FG	14,000.00		14,000.00
IBM PC		14,000.00	14,000.00	
	Purchases Subtotal	**$236,469.20**	**$ 118,234.60**	**$ 118,234.60**
	System Design & Installation	20,000.00	10,000.00	10,000.00
	160 hrs training	10,000.00	5,000.00	5,000.00
	Vendor Margin (AVI)	21,560.00	10,780.00	10,780.00
	Installation/Training/Margin Subtotal	**$ 51,560.00**	**25,780.00**	**25,780.00**
	TOTAL APPROVED SUBCONTRACTOR (AVI) SYSTEMS COSTS (Phase I)	**$288,029.20**	**$144,014.60**	**$ 144,014.60**

Appendix B

S O P

HIGH RESOLUTION DIGITIZED STEREO SLITLAMP

POWER UP CHECK LIST: (15 items)

* This is just a check list, the components may be turned on in any order **as long as the CPU is turned on last!!**

1. Slit lamp
2. BTX-3D stereo viewer (recorder)
3. Big monitor
4. Light sources (top knob X 2)
5. Cameras (stereo X 2)
6. BTY-3D stereo viewer (reviewer)
7. Little monitor
8. VCR
9. DKR (mini disk recorder)
10. Comp. Monitor
11. RAM computer
12. Printer
13. CPU

IMAGE CAPTURE: (toggle between video / cats eye by pressing labeled buttons on big / little monitors)

VIDEO:

1. Label two tapes with appropriate eye #.
2. Insert a tape.
3. Double check camera positions. (L on L)
4. Double check stereo alignment and color match.
   A. Push "select" button on BTX-3D box to select "split". (on top of big mon.)
   B. On the two cameras, (lowest boxes on cart) click switch from "cam" to "bars" (right hand side) on both cameras.
   C. *Adjust **only** the right (bottom) camera to bring it as close as possible to the left. "SC" will adjust the color match, "H" will adjust the alignment. (bottom right of camera)
   D. Click "cam" / "bars" switches back to "cam".
5. Type in date / eye #, tap foot switch, and record info for approx. 5 sec.
6. Tap foot switch again to pause recording.
7. Record exam fields.

* Be aware of the foot switch, make sure it stops when you tap it.
* Iris adjustment is necessary for optimal stereo. Remember to adjust camera irises one at a time. (closing right eye, adjusting left iris, then closing left eye and adjusting right iris)

HIGH RES. STILLS (CATS EYE):

1. Label two zip disks with appropriate eye #.
2. Double click on "clinical studies" folder. (on desk top)
3. From "file" on menu bar at top of comp. screen, select "new" to create two new folders for images you will capture. Label them accordingly.
4. Open PhotoShop. (on desk top)
5. From "file" on menu bar at top of comp. screen, select "import".
6. From pull down menu select "sonyDKC5000".
7. On remote hit "camera / memory" button to toggle between live camera and image buffer. (images captured)
8. In "memory" mode, hit "+" / "-" to toggle through images captured.
9. In "camera" mode hit "stand-by" to load buffer. (for capture)
10. Hit "release" to capture image.

SAVING CAPTURED IMAGES:

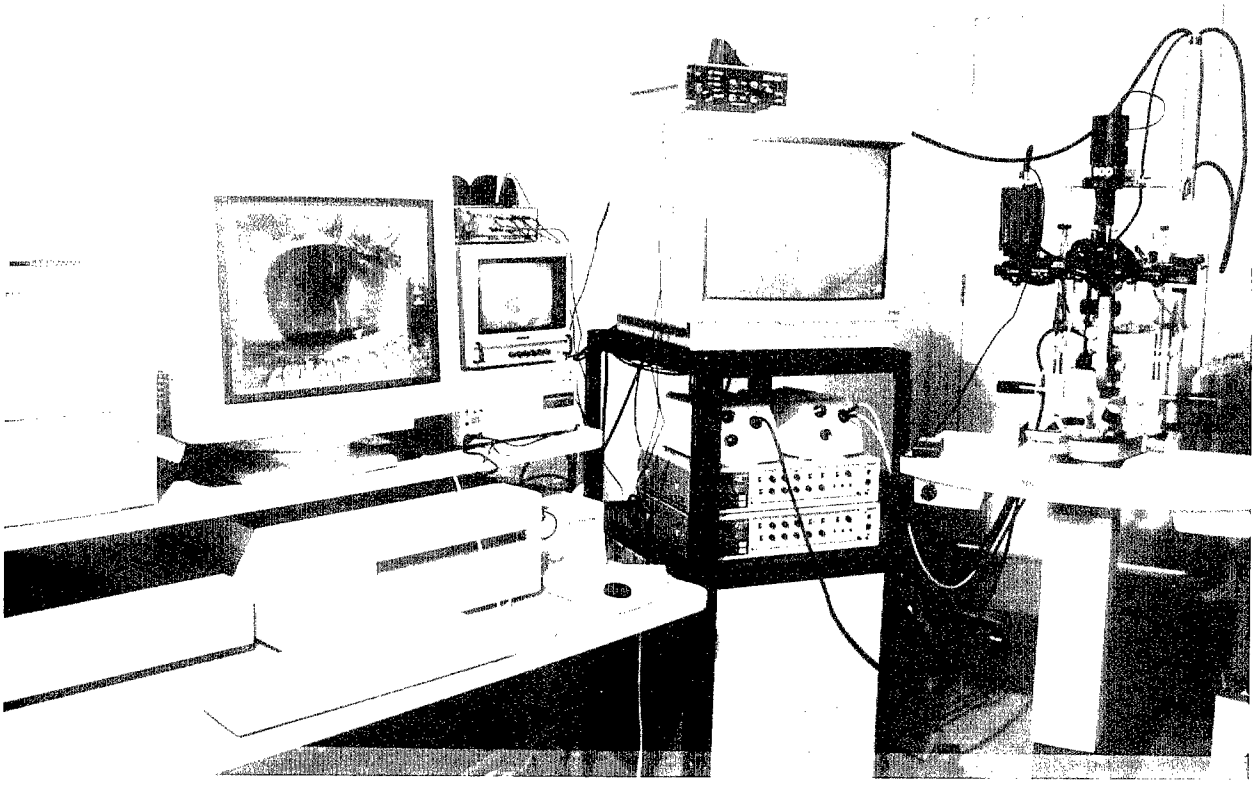
1. After capturing 10 images click "mark" then "all" and wait for the computer to retrieve them.
2. From "file" on menu bar at top of comp. screen, select "save as".
3. From pull down menu at top of box, select appropriate folder.
4. Type appropriate name / num. (I001, AC001, etc.) and click "save".
5. Under "Tiff options" Select "Macintosh" and check "LZW compression"
6. After session is complete and all images are captured, put them in order, close folder, insert zip disk, then drag folder to zip disk thumbnail. (this will copy all info. To the zip)

POWER DOWN CHECK LIST:

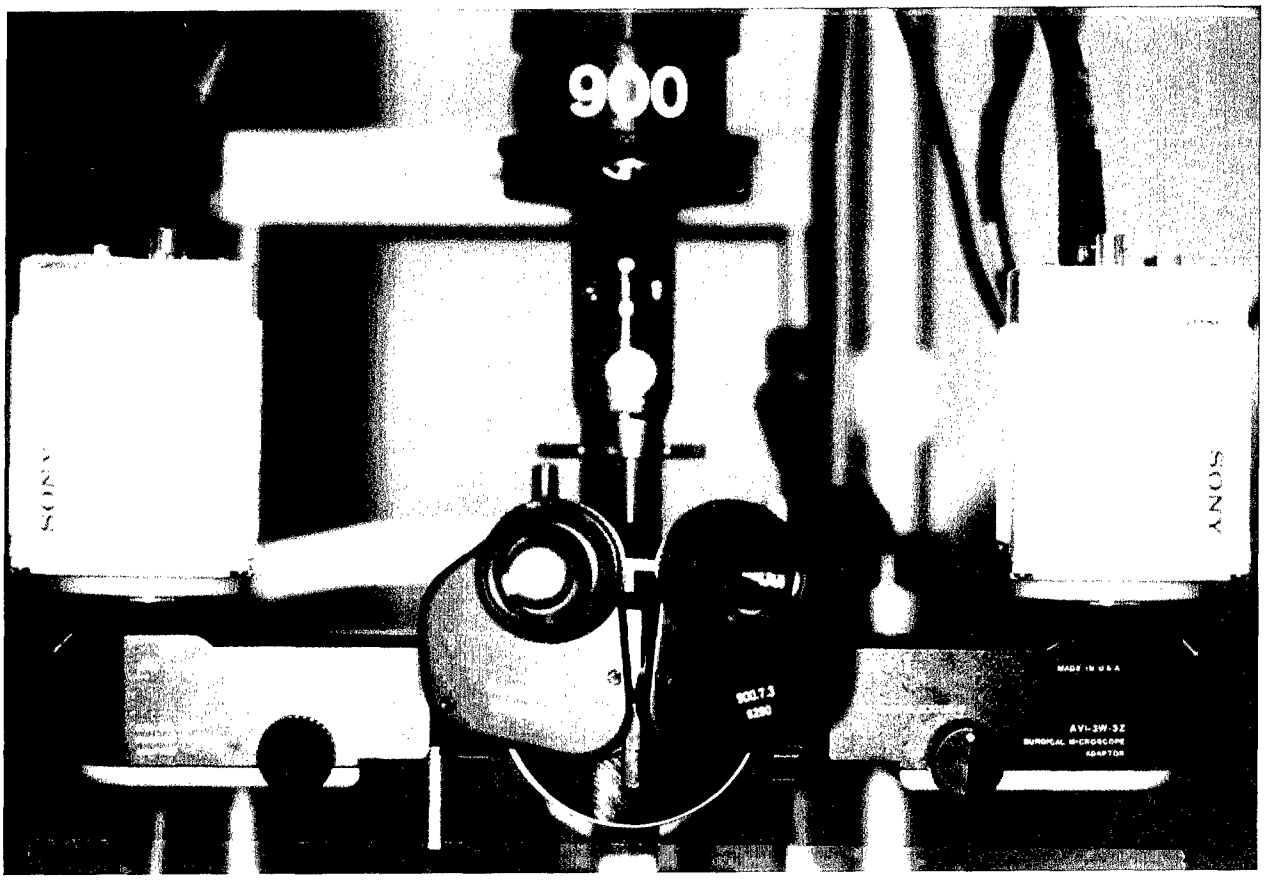
1. Make sure all images are saved to appropriate folders.
2. In the "special" pull down menu bar, select "shutdown" option
3. Shut down the rest of the equipment in any order, just make sure **everything** is off.

Appendix C

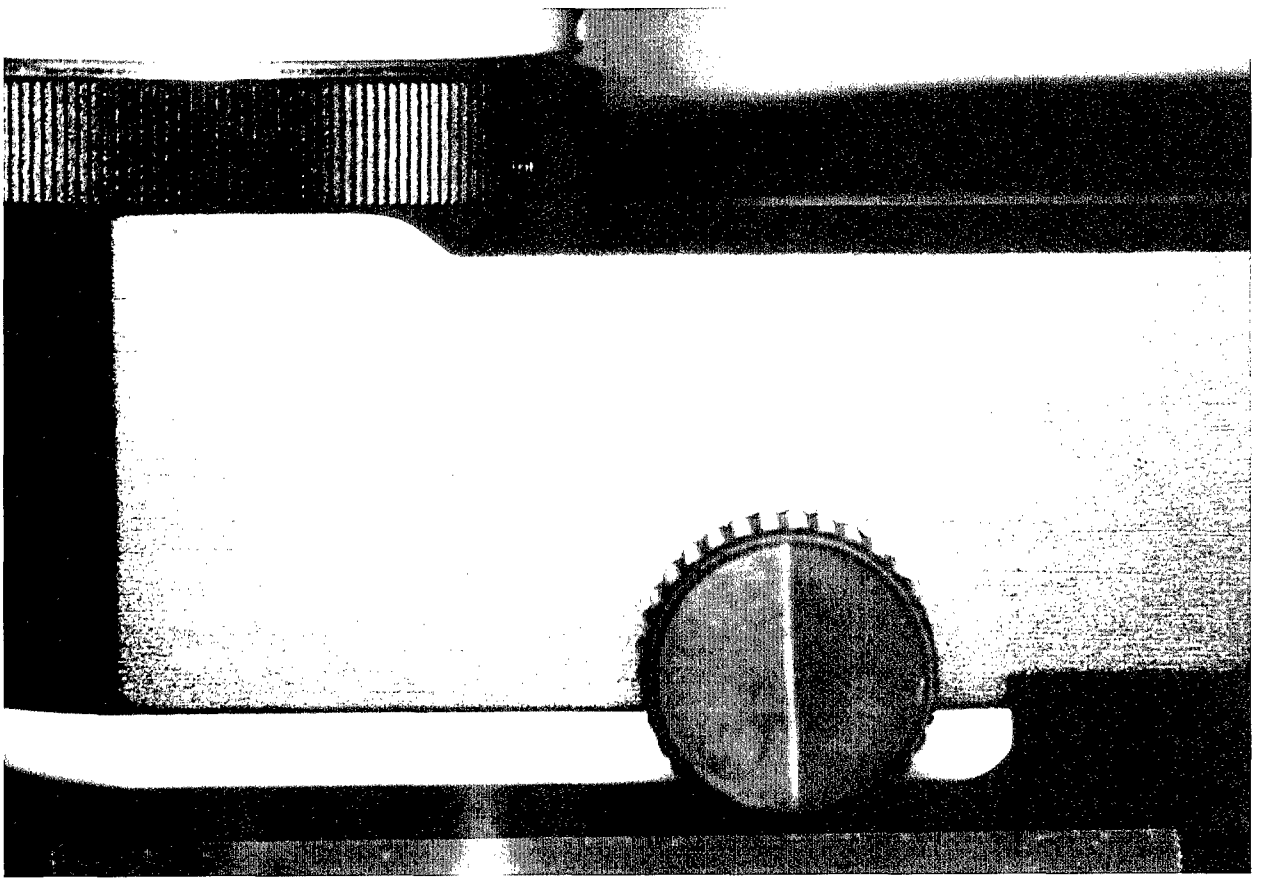
CONCEPT DEMONSTRATION SYSTEM



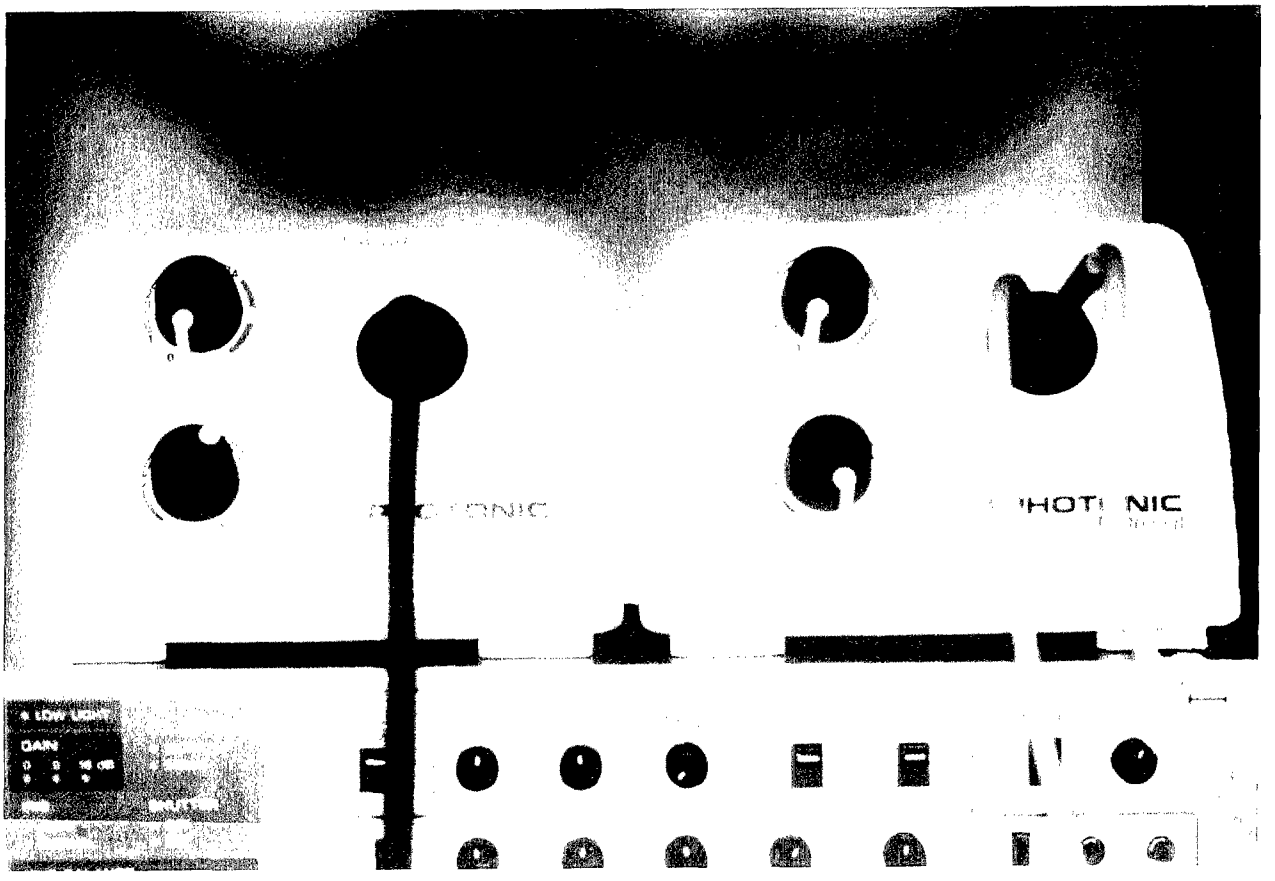
ORIGINAL CONCEPT DEMONSTRATION SYSTEM
STEREO CAMERA APPLICATION



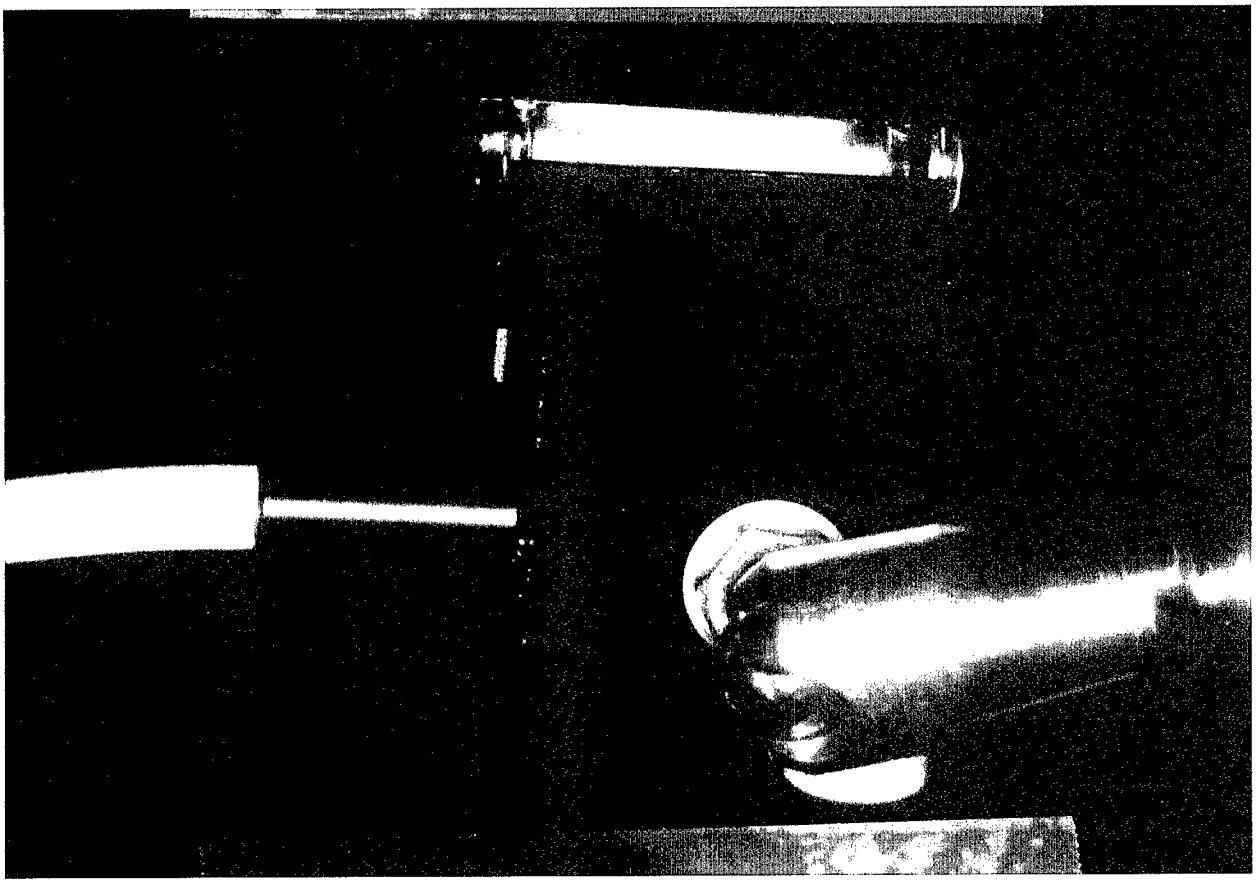
ORIGINAL CONCEPT DEMONSTRATION SYSTEM
OPTICAL CAMERA INTERFACE ADAPTER



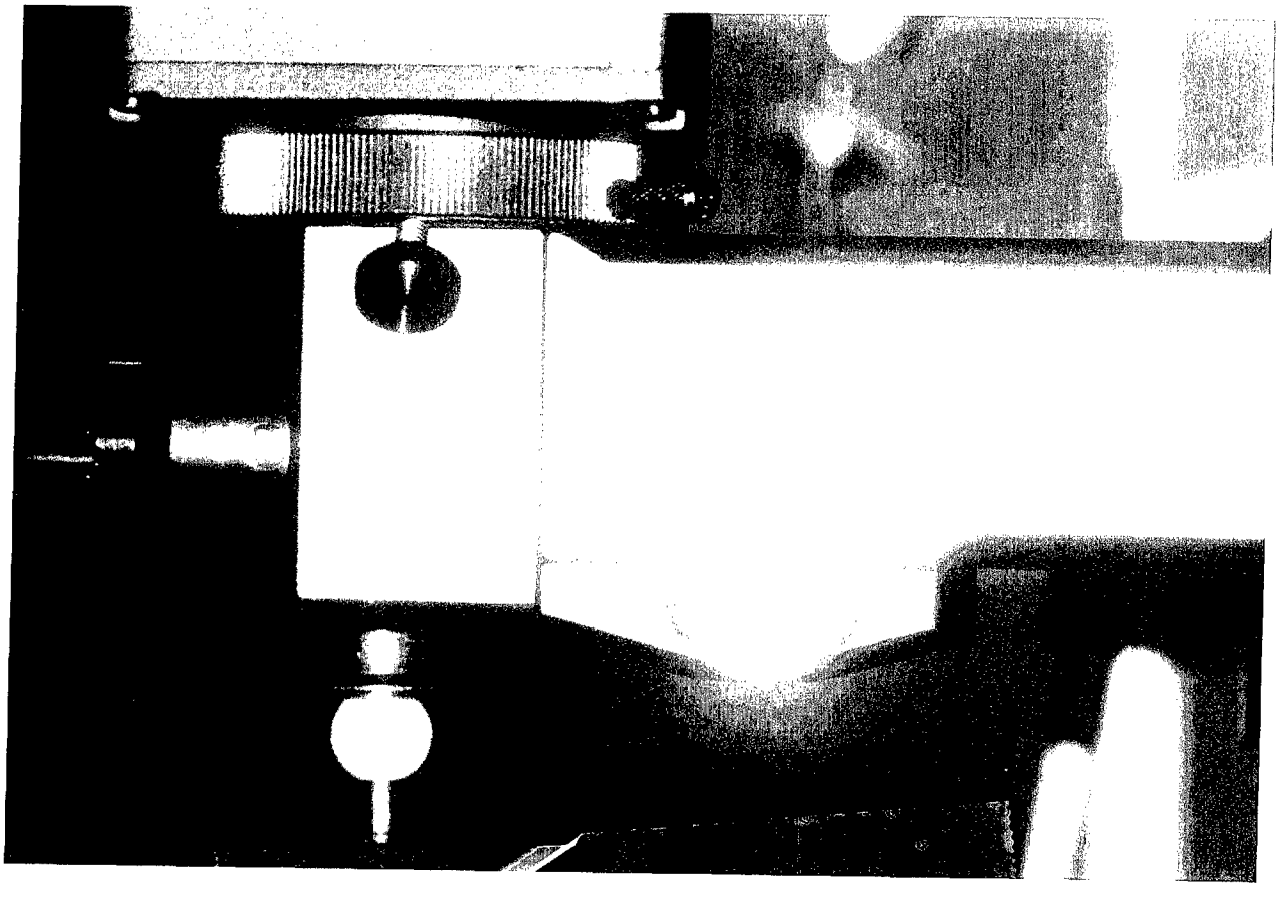
FIBEROPTIC ILLUMINATION LIGHT SOURCES



ORIGINAL CONCEPT DEMONSTRATION SYSTEM
FIBEROPTIC ILLUMINATION SYSTEM ILLUMINATION DIFFUSER



ORIGINAL CONCEPT DEMONSTRATION SYSTEM
HIGH RESOLUTION OPTICAL/CAMERA INTERFACE
120 X MAGNIFICATION MICROFOCUS CONTROL/ X-Y POSITION CONTROL



Protocol Notes

In-person exam:

- The examiner will have study participants sign the Informed Consent.
- Exam will be conducted with best magnification and resolution possible with the slit lamp. Examiner will note the settings used for each field.
- Presence or absence of pathology will be noted (Y/N). If present, diagnosis will be noted.
- Each examiner will include a few fellow eyes ("normals") for video, high resolution slit lamp exam. The fellow eye will be denoted with its own study ID#.
- The examiner will mark the photography request form with the patient study ID#, the eye to be examined, and the pathology or pathologies present.

Video and high resolution slit lamp exam:

- The photographer will perform a video exam to include the standard fields indicated for the in-person exam. Each exam will be marked with the patient study ID#, date, and the name of the in-person examiner.
- The photographer will then obtain still images of the indicated fields using the best magnification and resolution possible with the high-resolution slit lamp. The equipment settings will be noted for each image. Images will be labeled with the patient study ID#, date, and name of the in-person examiner, then downloaded and stored.
- A review of images by the in-person examiner will occur before the patient leaves to confirm that the pathology has been captured.

Reading of video and still image exams:

- Retrieved exams will be interpreted by ophthalmologists who did not do the in-person exams.
- The reader will review both the video and the still images, and indicate pathology or pathologies diagnosed. It will be noted if the diagnosis was made from the video and/or the still images.

High-Resolution Digitized Stereo Slit Lamp Clinical Study
IN-PERSON SLIT LAMP EXAM

Patient ID # _____ **Exam Date** _____

Examiner _____ **Eye** **OD** **OS**

Exam Fields	**Magnification**	**Background Illumination**	**Slit Illumination**	**Filter – Y / N Type**	**Peripheral Device - Y / N Type**	**Pathology**
Lids and lashes (wide angle)						
Lid margins						
Inverted lid (upper)						
Inverted lid (lower)						
Conjunctiva						
Cornea						
Slit-specific cornea						
Anterior chamber angle						
Anterior chamber cell and flare						
Iris						
Slit-specific iris						
Posterior chamber						
Slit-specific posterior chamber						
Slit-specific lens						
Dilated fields:						
Slit-specific lens						
Optic nerve head						
Macula						
Slit-specific peripheral retina						

High-Resolution Digitized Stereo Slit Lamp Clinical Study
STILL-IMAGE CAMERA SLIT LAMP EXAM

Patient ID # _____ **Exam Date** _____

Examiner _____ **Eye** **OD** **OS**

Exam Fields	Magnification	Background Illumination	Slit Illumination	Filter – Y / N Type	Peripheral Device - Y / N Type	Pathology
Lids and lashes (wide angle)						
Lid margins						
Inverted lid (upper)						
Inverted lid (lower)						
Conjunctiva						
Cornea						
Slit-specific cornea						
Anterior chamber angle						
Anterior chamber cell and flare						
Iris						
Slit-specific iris						
Posterior chamber						
Slit-specific posterior chamber						
Slit-specific lens						
Dilated fields:						
Slit-specific lens						
Optic nerve head						
Macula						
Slit-specific peripheral retina						

High-Resolution Digitized Stereo Slit Lamp Clinical Study
RETRIEVED SLIT LAMP EXAM

Patient ID # _____ **Exam Date** _____

Reader _____ **Review Date** _____

Exam Field	Pathology on video	Pathology on still-image
Lids and lashes (wide angle)		
Lid margins		
Inverted lid (upper)		
Inverted lid (lower)		
Conjunctiva		
Cornea		
Slit-specific cornea		
Anterior chamber angle		
Anterior chamber cell and flare		
Iris		
Slit-specific iris		
Posterior chamber		
Slit-specific posterior chamber		
Slit-specific lens		
Dilated fields:		
Slit-specific lens		
Optic nerve head		
Macula		
Slit-specific peripheral retina		

1) Lids & Lashes
2) U.L. Margin
3) L.L. Margin
4) Everted L.L. & Fornix
5) Sup. Conj.
6) Cornea-Tear film
7) A.C. Angle
8) Slit-spec. Corn. (temp)
9) Slit-spec. Corn. (cent.)
10) Slit-spec. Corn. (nasal)
11) Iris
12) Slit-spec. Iris
13) Slit-spec. Lens
14) Retro-ill. Lens
15) Other 1
16) Other 2

Results of Teleopthamology Experiment

Experiment:

82 eyes were examined both in office and by two separate individuals using teleopthamology. Abnormalities were divided into those for the lids, conjunctiva/sclera, cornea, anterior chamber, iris and lens.
The number of abnormalities for each eye part was counted for each analyst, and the results were compared for the three analyses.

A summary of the findings of the statistical analysis follows.

LIDS

Blepharitis/MGD, Blepharoplasty, Dermatochalasis, Entropion/Ectropion, Lid lesions, Trichiasis, and other.

inperson * 1st tele analyst Crosstabulation - Lids
Count

		1st tele analyst			Total
		0	1	2	
inperson	0	**27**	**29**	**7**	63
	1	**6**	**9**	**1**	16
	2	**0**	**1**	**2**	3
Total		33	39	10	82

	Value	Approx. T	Approx. Sig.
Spearman	0.12	1.12	0.27
Kappa	0.10	1.35	0.18

The results of the inperson analysis and of the first teleanalysis are not well-correlated for lids.

Sensitivity	68.42
Specificity	42.86

PPV	26.53	

inperson * 2nd tele analyst Crosstabulation - Lids

Count

		2nd tele analyst				Total
		0	1	2	3	
inperson	0	**44**	**10**	**5**	**4**	63
	1	**3**	**8**	**3**	**2**	16
	2	**2**	**1**	**0**	**0**	3
Total		49	19	8	6	82

	Value	Approx. T	Approx. Sig.
Spearman	0.32	3.02	0.00
Kappa	.		

The results of the inperson analysis and of the second teleanalysis are weakly positively correlated for lids.

Sensitivity	73.68
Specificity	69.84
PPV	42.42

Average for LIDS:

Sensitivity	71.05
Specificity	56.35
PPV	34.48

Wilcoxon Signed Ranks Test

1st tele analyst < inperson	7
1st tele analyst > inperson	37
inperson = 1st tele analyst	38
2nd tele analyst < inperson	6
2nd tele analyst > inperson	24
inperson = 2nd tele analyst	52

Test Statistics

	1st telean	2nd tele an
Z	-4.57	-3.22
Asymp. Si	0.00	0.00

It is not unreasonable to assume, for either teleanalyst, that they provide results different from that of the inperson analyst for the lids.

CONJUNCTIVA / SCLERA

Bleb, conj. Pigment, conj. lesion / cyst, follicles/papillae, pingueculum / pterygium, and other.

inperson * 1st tele analyst Crosstabulation - Conjunctiva / Sclera
Count

		1st tele analyst			Total
		0	1	2	
inperson	0	**35**	**25**	**0**	60
	1	**4**	**9**	**7**	20
	2	**0**	**2**	**0**	2
Total		39	36	7	82

	Value	Approx. T	Approx. Sig.
Spearman	0.45	4.56	0.00
Kappa	0.15	1.73	0.08

The results of the inperson analysis and of the first teleanalysis are weakly positively correlated for conjunctiva/sclera.

Sensitivity	81.82
Specificity	58.33
PPV	41.86

inperson * 2nd tele analyst Crosstabulation - Conjunctiva / Sclera
Count

		2nd tele analyst			Total
		0	1	2	
inperson	0	**47**	**12**	**1**	60
	1	**5**	**13**	**2**	20
	2	**1**	**1**	**0**	2
Total		53	26	3	82

	Value	Approx. T	Approx. Sig.
Spearman	0.47	4.72	0.00
Kappa	0.40	4.09	0.00

The results of the inperson analysis and of the second teleanalysis are weakly positively correlated for conjunctiva/sclera.

Sensitivity	72.73
Specificity	78.33
PPV	55.17

Average for CONJUNC./SCLERA

Sensitivity	77.27
Specificity	68.33
PPV	48.52

Wilcoxon Signed Ranks Test

1st tele analyst < inperson	6
1st tele analyst > inperson	32
inperson = 1st tele analyst	44
2nd tele analyst < inperson	7
2nd tele analyst > inperson	15
inperson = 2nd tele analyst	60

Test Statistics

	1st telean	2nd tele an
Z	-4.22	-1.50
Asymp. Si	0.00	0.13

It is not unreasonable to assume, for the **first teleanalyst**, that s/he provides results different from that of the inperson analyst for conjunctiva/sclera.

CORNEA

Abrasion, arcus, band keratopathy, corneal dystrophy / guttae, corneal scar / stromal opacity, endothelial pigment deposit, keratic precipitates, keratoconus, punctate keratopathy, Saltzmann's nodules, vascularization, and other.

inperson * 1st teleanalyst Crosstabulation - Cornea
Count

		1st teleanalyst				Total
		0	1	2	4	
	0	**30**	**9**	**1**	**0**	40
inperson	1	**4**	**23**	**2**	**0**	29
	2	**1**	**3**	**3**	**0**	7
	3	**0**	**4**	**0**	**0**	4
	4	**0**	**0**	**1**	**1**	2
Total		35	39	7	1	82

	Value	Approx. T	Approx. Sig.
Spearman	0.64	0.08	0.00
Kappa	.		

The results of the inperson analysis and of the first teleanalysis are positively correlated for the cornea.

Sensitivity	88.10
Specificity	75.00
PPV	78.72

inperson * 2nd teleanalyst Crosstabulation - Cornea
Count

		2nd teleanalyst				Total
		0	1	2	4	
	0	**29**	**11**	**0**	**0**	40
	1	**4**	**16**	**8**	**0**	28
inperson	2	**1**	**2**	**4**	**0**	7
	3	**0**	**1**	**3**	**0**	4

	4	0	0	0	1	1
Total		34	30	15	1	80

	Value	Approx. T	Approx. Sig.
Spearman	0.71	0.07	0.00
Kappa	0.69	0.07	0.00

The results of the inperson analysis and of the second teleanalysis are quite positively correlated for the cornea.

Sensitivity	87.50
Specificity	72.50
PPV	76.09

Average for CORNEA:

Sensitivity	87.80
Specificity	73.75
PPV	77.41

Wilcoxon Signed Ranks Test

1st tele analyst < inperson	13
1st tele analyst > inperson	12
inperson = 1st tele analyst	57
2nd tele analyst < inperson	11
2nd tele analyst > inperson	19
inperson = 2nd tele analyst	50

Test Statistics

	1st telean	2nd teleana
Z	-1.02	0.32
Asymp. Si	0.31	0.32

It is unreasonable to reject the hypothesis that both teleanalysts are basically in agreement with the inperson analyst for the cornea.

ANTERIOR CHAMBER

AC Inflammation, Hyphema, Narrow angle and other.

inperson * 1st teleanalyst Crosstabulation
Count

		1st teleanalyst		Total
		0	1	
inperson	0	**78**	**1**	79
	1	**1**	**2**	3
Total		79	3	82

	Value	Approx. T	Approx. Sig.
Spearman	0.65	7.73	0.00
Kappa	0.65	7.73	0.00

The results of the inperson analyst and of the first teleanalysis are quite positively correlated for the anterior chamber.

Sensitivity	66.67
Specificity	98.73
PPV	66.67

inperson * 2nd teleanalyst Crosstabulation - Anterior Chamber
Count

		2nd teleanalyst		Total	Total
		0	1		
inperson	0	**78**	**0**	78	
	1	**1**	**1**	2	
Total		79	1	80	

	Value	Approx. T	Approx. Sig.
Spearman	0.70	0.25	0.00
Kappa	0.66	0.32	0.00

The results of the inperson analyst and of the second teleanalysis are quite positively correl for the anterior chamber.

Sensitivity	50.00
Specificity	100.00
PPV	100.00

Average for ANTR. CHAMBER:

Sensitivity	58.33
Specificity	99.37
PPV	83.33

Wilcoxon Signed Ranks Test

1st tele analyst < inperson	1
1st tele analyst > inperson	1
inperson = 1st tele analyst	80
2nd tele analyst < inperson	1
2nd tele analyst > inperson	0
inperson = 2nd tele analyst	79

Test Statistics

	1st telean	2nd teleana
Z	0.00	-1.00
Asymp. Si	1.00	0.32

It is unreasonable to reject the hypothesis that both teleanalysts are basically in agreement with the inperson analyst for the anterior chamber.

IRIS

Iris atrophy, iris lesion / cyst / nevus, peripheral iridectomy, posterior synechiae, and other.

inperson * 1st teleanalyst Crosstabulation - Iris
Count

		1st teleanalyst				Total
		0	1	2	3	
inperson	0	**59**	**10**	**1**	**0**	70
	1	**1**	**4**	**2**	**0**	7
	2	**0**	**2**	**1**	**0**	3
	3	**1**	**0**	**0**	**1**	2
Total		61	16	4	1	82

	Value	Approx. T	Approx. Sig.
Spearman	0.57	6.24	0.00
Kappa	0.40	5.06	0.00

The results of the inperson analysis and of the first teleanalysis are positively correlated for the iris.

Sensitivity	83.33
Specificity	84.29
PPV	47.62

inperson * 2nd teleanalyst Crosstabulation - Iris
Count

		2nd teleanalyst			Total	Total
		0	1	2		
inperson	0	**54**	**13**	**1**	68	
	1	**3**	**3**	**1**	7	
	2	**2**	**1**	**0**	3	
	3	**1**	**0**	**1**	2	
Total		60	17	3	80	

	Value	Approx. T	Approx. Sig.
Spearman	0.26	2.37	0.02
Kappa	.		

The results of the inperson analysis and of the second teleanalyst are weakly positively correlated for the iris.

		Average for ANTR. CHAMBER:	
Sensitivity	50.00	Sensitivity	66.67
Specificity	79.41	Specificity	81.85
PPV	30.00	PPV	38.81

Wilcoxon Signed Ranks Test

1st tele analyst < inperson	4
1st tele analyst > inperson	13
inperson = 1st tele analyst	65
2nd tele analyst < inperson	8
2nd tele analyst > inperson	15
inperson = 2nd tele analyst	57

Test Statistics

	1st telean	2nd teleana
Z	-1.83	-0.75
Asymp. Si	0.07	0.45

It is unreasonable to reject the hypothesis that both teleanalysts are basically in agreement with the inperson analyst for the iris.

LENS

Cataract (cortical, NS or PSC), lens subluxation (IOL or crystalline), pigment on lens capsule, posterior capsule opacification, pseudoexfoliation, pseudophakia, YAG capsulotomy, and other.

inperson * 1st teleanalyst Crosstabulation - Lens
Count

		1st teleanalyst				Total
		0	1	2	3	
inperson	0	**25**	**1**	**1**	**0**	27
	1	**1**	**17**	**6**	**0**	24
	2	**2**	**7**	**14**	**2**	25
	3	**0**	**3**	**1**	**1**	5
Total		28	28	22	3	81

	Value	Approx. T	Approx. Sig.
Spearman	0.72	9.31	0.00
Kappa	0.57	7.99	0.00

The results of the inperson analysis and of the first teleanalysis are quite positively correlated for the lens.

Sensitivity	96.30
Specificity	92.59
PPV	96.30

inperson * 2nd teleanalyst Crosstabulation - Lens
Count

		2nd teleanalyst				Total
		0	1	2	3	
inperson	0	**23**	**3**	**1**	**0**	27
	1	**4**	**14**	**5**	**0**	23
	2	**1**	**10**	**12**	**1**	24
	3	**0**	**3**	**1**	**1**	5
Total		28	30	19	2	79

	Value	Approx. T	Approx. Sig.
Spearman	0.70	8.51	0.00
Kappa	0.47	6.46	0.00

The results of the inperson analysis and of th second teleanalysis are quite positively correl for the lens.

		Average for LENS:	
Sensitivity	90.38	Sensitivity	93.34
Specificity	85.19	Specificity	88.89
PPV	92.16	PPV	94.23

Wilcoxon Signed Ranks Test

1st tele analyst < inperson	14
1st tele analyst > inperson	10
inperson = 1st tele analyst	57
2nd tele analyst < inperson	19
2nd tele analyst > inperson	10
inperson = 2nd tele analyst	50

Test Statistics

	1st telean	2nd teleana
Z	-1.30	-1.81
Asymp. Si	0.19	0.07

It is unreasonable to reject the hypothesis that both teleanalysts are basically in agreement with the inperson analyst for the lens.

Statistics: Sue Toledo, HRC, Univerrsity of Utah October 19. 1999 (801) 587-9124

DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
820 CHANDLER STREET
FORT DETRICK, MARYLAND 21702-5014

REPLY TO
ATTENTION OF:

October 3, 2000

R & D Branch A

SUBJECT: Contract No. DAMD17-97-C-7046
Modification P00005

2000

Ms. Amy J. Sikalis
University of Utah
Office of Sponsored Programs
1471 Federal Way
Salt Lake City, Utah 84102

Dear Ms. Sikalis:

Enclosed is a fully executed original of the above subject contract modification for your records and a copy for the Principal Investigator.

If you have any questions concerning this matter, please contact the undersigned at 301-619-2175 or e-mail: pat.evans@amedd.army.mil.

Sincerely,

for Patricia A. Evans
Contract Specialist

Enclosure

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
0	1 | 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00005			

6. ISSUED BY CODE DAMD17
US ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
DIRECTOR
820 CHANDLER STREET
FORT DETRICK, MD 21702-5014

7. ADMINISTERED BY (If other than Item 6) CODE
See Item 6

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)
UNIVERSITY OF UTAH
JOHN A MORAN EYE CENTER
50 NORTH MEDICAL DRIVE
SALT LAKE CITY UT 84132

CODE 3T624 FACILITY CODE

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MOD. OF CONTRACT/ORDER NO. DAMD17-97-C-7046

X 10B. DATED (SEE ITEM 13) 25-Sep-2000

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the document; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN THE REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
Bilateral FAR 43.103(a)(3)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
See Pages 2 and 3 of this modification.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
LYNNE U. CHRONISTER, DIRECTOR OFFICE OF SPONSORED PROJECTS		
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED 9/29/00	16B. UNITED STATES OF AMERICA BY (Signature of Contracting Officer)	16C. DATE SIGNED 20 Oct '00

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

Pursuant to mutual agreement, the following changes are made in the provisions of this contract:

1. Section B., Term of Contract is changed as follows:

   From: 2 June 1997 – 1 October 2000 (Research Ends 1 May 2000)

   To: 2 June 1997 – 31 December 2000 (Research Ends 15 November 2000)

2. Revised Budget for Line Item 0002 is incorporated into this modification as APPENDIX A.

3. Section C.1. Scope of Work for Line Item 0002 is replaced with the following:

Statement of Work for High-Resolution Slit Lamp Systems
15 September 2000

The Contractor will provide best effort in combining technology and equipment for this revised SOW. Contractor will assemble and optimize two operational prototype systems, using a combination of off-the-shelf items with the following specifications. System one (flash option) will consist of an FS-3V Nikon zoom photo slit lamp with a Nikon D-1 digital camera. System one must have an additional indirect lighting source for illuminating the anterior segment of the eye. System two (non-flash option) shall consist of a Haag Streit BQ 900 photo slit lamp with a Kodak DCS-620x digital camera optically adapted to the slit lamp. System two must have an enhanced illumination system, which will be coupled to the slit lamp for lighting optimization. In addition, a high resolution video monitoring system will be adapted to system two for assure high quality digital images.

Both cameras will have an IEEE 1394 connector for downloading images to a workstation and eight PCMCIA cards. The workstation will have a processor equivalent or greater than 900 MHz Pentium. In the workstation, there will be a minimum of: 1 GB RAM, 36 GB hard drive, 20/48x IDE CD-ROM reader, 4x/2x/24x IDE CD-ROM writer, 64 MB video card, 5.25" PCMCIA card reader, 10/100 network card, FAX modem card (56KB), USB port, IEEE 1394 port (including card and driver), and appropriate connection capability. Included in the workstation will be a 21" color high-resolution monitor (plus a passive screen) with a vertical refresh rate of 70-90 MHz compatible with image capturing and management software (Windows 2000 compatible). Archival software for storing the images shall be Windows 2000 compatible. The operating system shall be Windows 2000 compatible.

In addition the 2 laptops will be Pentium 750 or greater CPU, with 512 or greater RAM maximized to the laptop, 30GB hard drive, 32x CD-ROM reader, active color high-resolution screen, USB port, Imation 120 floppy port (if possible), IEEE 1394 card and port with driver, and Windows 2000 and archival software compatible with the workstation. Also included on each laptop will be an Internal 56K v. 90 capable fax modem, 10/100 fast Ethernet PC card, and an additional 79 watt Lithium Ion battery.

The high-resolution slit lamp imaging systems should yield clear well-defined images of the anterior segment of the eye to include the corneal stroma (best effort to view). Cell/cells in the anterior segment should be visualized on the digital photos. Detail of the iris and lens should be noted to include crypts, lens opacities, and posterior capsular cataracts. The images should be readily transferable to a passive stereo viewing system. The viewer should not be using active stereo glasses, but rather filtering glasses (4 per station) viewing a polarizing screen located on the monitor. The archival software should permit thumbnail picture evaluation with easy storage of selected images, i.e. Adobe Photoshop archival retrieval system, and all Windows 2000 compatible. The laptop should be able to view images from the hard drive, CD-ROM, and include the archival software, on each laptop and workstation.

4. Section F.3. Contract Deliverable for Line Item 0002 is changed as follows:

All deliverables required pursuant to this contract (See Sections B and C) shall be shipped to the following address(es) in accordance with the following schedule:

Deliverable	Reference	Quantity	Delivery Date
0002	Optional Demonstration System(s)		
0002AA	System one (Nikon)	1	15 Oct 2000
0002AB	System two (Haag Streit)	1	15 Nov 2000
0002AC	User's Guide(s)	2	Upon delivery of System(s)
0002AD	Functional Specifications	2	Upon delivery of System(s)
0002AE	Production Design	2	Upon deliver of System(s)

SHIP TO ADDRESS(ES)

ITEM 0002AA
Telemedicine & Advanced Technology Research Center (TATRC)
ATTN: Eugene S. Channing, O.D.
1054 Patchel Street
Ft. Detrick, MD 21702-5012

ITEM 0002AB
Wendall C. Bauman, Col (Sel), USAF, MC
Brooke Army Medical Center
Ophthalmology Services/ MCHE-SDO
3851 Roger Brook Drive
Fort Sam Houston, TX 78234-6200

All other terms and conditions of the Contract remain unchanged.

Qty	Make	Model	Description	Price (our cost)	Total
1	HS	900 BQ	0900.0010NH BQ slit lamp w/stand & casters No Hruby lens	$ 11,306.00	$ 11,306.00
1	HS	9004.1	Applination Tonometer for BQ slit lamp	$ 1,170.00	$ 1,170.00
1	HS	9007.10.70/30	Beam Splitter 70/30	$ 1,380.00	$ 1,380.00
1	HS		special beam splitter 90/10	$ 1,380.00	$ 1,380.00
1	HS	9007.4C	cross hair eye-piece	$ 710.00	$ 710.00
1	HS	9007.5	Stereo Variator	$ 910.00	$ 910.00
1	HS		Cable conduit for video cable	$ 275.00	$ 275.00
					$ -
1	HS	900.0033	Photo upgreade package (no flash) mirror housing w/diaphragm control obj tube f/mono p	$ 13,950.00	$ 13,950.00
1	HS	656600	35mm side photo tube(attaches to beam splitter)	$ 2,400.00	$ 2,400.00
					$ -
1	AVI	FIB-OPT	Fiber Optics: Stage 1 prototype: illuminator box and center bundle	$ 3,400.00	$ 3,400.00
1	AVI		dual fiber bundle Proto-type, one of a kind	$ 1,500.00	$ 1,500.00
1	AVI		special package for focus & light composition on live video screen(camera, monitor, adapt	$ 8,000.00	$ 8,000.00
4	Adobe	Photoshop 6.0	graphics software for laptops & workstations	$ 600.00	$ 2,400.00
4		Paint Shop Pro	graphics software for batch processing and thumbnail viewing	$ 70.00	$ 280.00
2			79 Watt Lithium Ion Battery	$ 300.00	$ 600.00
1	Kodak	DCS620x	Digital still image camera 1728x1152, ISO 200-1600 cat# 136-4109	$ 6,486.00	$ 6,486.00
4	Lexar		160MB memory cards for Kodak DCS620x cat# 834-9052	$ 595.00	$ 2,380.00
1	Kodak		battery 6-pack for Kodak DCS620x cat# 821-7374	$ 645.00	$ 645.00
2	Dell	Precision 420	Dell workstation w/933MHZ, 1GB RAM, 36GB HD, 21" mon., WinNT4, Firewire, PCMCIA rdr	$ 7,928.00	$ 15,856.00
2	Dell	Inspiron 7500	Dell laptop w/750MHZ, 512MB RAM, 30GB HD, 15" SXGA, 8MB ATI, CDROM, ether+modem, W	$ 5,825.00	$ 11,650.00
1	Nikon	FS-3V #88397	Zoom photo slit lamp FS-3V table model package 1 with Nikon D1 digital camera kit	$ 18,380.70	$ 18,380.70
1	Nikon	prod# 88337	video background illumination & fiber holder for FS-3V and NS-1V	$ 446.20	$ 446.20
2	Nikon		NiMh battery	$ 98.00	$ 196.00
4	Lexar		8x 128MB memory card	$ 385.00	$ 1,540.00
1			USB card reader	$ 85.00	$ 85.00
2			PCMCIA card adapter	$ 25.00	$ 50.00
1	Nikon	prod# 88315	non-contact specular attachment for endothelial cell photography	$ 1,004.30	$ 1,004.30
1	Nikon	88344	90D lens holder	$ 70.00	$ 70.00
1	Nikon	88343	retro illumination mirror	$ 130.00	$ 130.00
1	Nikon	79926	Barrier filter for FS-3V	$ 150.00	$ 150.00
1	AVI		Travel (Ft. Detrick and Ft. Sam Houston)	$ 1,900.00	$ 1,900.00
1	SHIP	SHIP	shipping, handling, packaging & insurance for all above equipment from manufacturers to	$ 1,600.00	$ 1,500.00
1	SHIP	SHIP	shipping, handling, packaging & insurance for all above equipment from AVI Inc. to TX & MI	$ 3,000.00	$ 3,000.00
1	AVI	labtop-computer	complete setup of all 4 computers, software installation, hardware installation, testing, re-pa	$ 3,000.00	$ 3,000.00
1	AVI	labtop-on site	on site installation, setup and training	$ 10,000.00	$ 10,000.00
1	AVI	labtop-HS slit lamp	engineering, modification of mirror housing for top mounted camera & electronic control un	$ 10,000.00	$ 10,000.00
1	AVI	labtop-testing	testing & optimizing of equipment in AVI(NYC)	$ 7,000.00	$ 7,000.00
1	AVI		vendor margin	$ 6,639.37	$ -
				$	145,128.20

DAMD17-97-C-7046
Modification P00005
APPENDIX A